

14113626

510(k) SUMMARY

SUBMITTER: Sorin Group Italia S.r.l. APR - 5 2012
86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

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DATE PREPARED: March 14, 2012

DEVICE TRADE NAME: INSPIRE 6 hollow fiber oxygenator with integrated hardshell venous/cardiectomy reservoir

COMMON NAMES: Hollow Fiber Oxygenator with Hardshell Venous/Cardiectomy Reservoir
Hollow Fiber Oxygenator
Hardshell Venous/Cardiectomy Reservoir

CLASSIFICATION NAMES: Cardiopulmonary Bypass Oxygenator/
Cardiopulmonary Bypass Heat Exchanger/
Cardiopulmonary Bypass Blood Reservoir/
Cardiopulmonary Bypass Defoamer

PREDICATE DEVICE: D 905 EOS: hollow fiber oxygenator with integrated hardshell venous/cardiectomy reservoir

DEVICE DESCRIPTION:

The INSPIRE 6 is consisting of an oxygenator (INSPIRE 6M) and a hardshell venous/cardiectomy reservoir (INSPIRE HVR). The reservoir is connected to the gas exchange module by means of a molded fitting joint.

The INSPIRE 6 is a high efficiency microporous hollow fiber membrane oxygenator integrated with an heat exchanger and connected to an hardshell venous/cardiectomy reservoir.

The device can be operated at flow rates up to 6 liters per minute.

The hollow fiber membrane oxygenator provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger controls blood temperature and allows the use of hypothermia or aids in the maintenance of normothermia during surgery.

The integrated hardshell reservoir collects, defoams, filters venous and suction blood, and can be used post-operatively for chest drainage.

The INSPIRE 6 is a modified version of the currently marketed D905 EOS.

INDICATION FOR USE:

The intended use for the two elements that constitute the integrated device are:

INSPIRE 6M: Hollow Fiber Oxygenator

INSPIRE 6M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 6M is intended to be used for 6 hours or less.

INSPIRE HVR: Hardshell Venous/Cardiotomy Reservoir

INSPIRE HVR is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood. INSPIRE HVR can be used post-operatively for chest drainage.

INSPIRE HVR is intended to be used for 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS:

The INSPIRE 6 has the same fundamental technological characteristics, principles of operation and control mechanisms as the predicate device.

Sorin believes that the INSPIRE 6 is substantially equivalent to the D905 EOS on the basis of operating principles and basic function.

The INSPIRE 6 and the D905 EOS share the same fundamental technological characteristics except for some modifications that do not affect the basic device function. Any differences do not raise any new issues of safety and effectiveness.

The INSPIRE 6 is ethylene oxide sterilized and has a non-pyrogenic fluid path. It is for single use only.

NON CLINICAL TEST RESULTS:

Applicable tests were carried out in accordance with the requirements of ISO 10993-1 and the FDA May 1st, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of materials.

IN VITRO TEST RESULTS:

In vitro testing was carried out in accordance with the relevant requirements of "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff" issued on November 13, 2000, "Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final Guidance for Industry and FDA" issued on November 29, 2000, and ISO 15674, "Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags".

In vitro testing was carried out to demonstrate both the substantial equivalence with the predicate device and also to comply with safety and effectiveness requirements. Testing supplied in the 510(k) premarket notification includes performance tests and mechanical integrity tests that demonstrate compliance with performance specifications.

The tests that were performed are listed in the following summarizing table. For each test mentioned in the table the test outcome in terms of pass or fail is also provided.

| TEST | TEST CLASSIFICATION | TEST TITLE |
|------|------------------------|---|
| 1 | Physical/Mechanical | Structural Integrity |
| 2 | Physical/Mechanical | Blood, water, gas pathway integrity |
| 3 | Physical/Mechanical | Blood pathway integrity |
| 4 | Functional/Performance | Blood volume capacity |
| 5 | Functional/Performance | Reservoir blood rest volume |
| 6 | Functional/Performance | Gas transfer performance/blood side pressure drop |
| 7 | Functional/Performance | Heat exchange performance/water side pressure drop |
| 8 | Functional/Performance | Reservoir Air handling |
| 9 | Functional/Performance | Reservoir Break-through time and volume |
| 10 | Functional/Performance | Reservoir Defoaming efficiency |
| 11 | Functional/Performance | Reservoir Dynamic priming volume / Hold-up |
| 12 | Functional/Performance | Reservoir Filtration Efficiency - venous section |
| 13 | Functional/Performance | Reservoir Filtration Efficiency - cardiectomy section |
| 14 | Functional/Performance | Reservoir Flow rate capacity |
| 15 | Functional/Performance | Reservoir Pressure drop |
| 16 | Functional/Performance | Hemolysis |
| 17 | Functional/Performance | Reservoir Hemolysis |
| 18 | Functional/Performance | Blood compatibility |
| 19 | Functional/Performance | Reservoir Blood compatibility |
| 20 | Functional/Performance | Leaching of coating |
| 21 | Functional/Performance | Reservoir Leaching of coating |
| 22 | Functional/Performance | Flaking of coating |
| 23 | Functional/Performance | Reservoir Flaking of coating |
| 24 | Functional/Performance | Flaking of coating on integrated device |
| 25 | Functional/Performance | Uniformity of coating |

The in-vitro testing was successfully completed and INSPIRE 6 passed all the above listed tests.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the INSPIRE 6 performs in a manner substantially equivalent to the predicate device with respect to the relevant functional parameters. Test results of this study suggest the INSPIRE 6 is equivalent to the predicate device with respect device function.

Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

APR - 5 2012

Sorin Group Italia s.r.l.
c/o Mr. Barry Sall
Principal Consultant
Parexel International Consulting
195 West Street
Waltham, WA 02451

Re: K113626

Trade/Device Name: Inspire 6 Hollow Fiber Oxygenator with Integrated Hardshell Venous
Cardiotomy/Reservoir
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: March 14, 2012
Received: March 15, 2012

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113626

Device Name: INSPIRE 6 hollow fiber oxygenator with integrated hardshell
venous/cardiectomy reservoir

Indications for Use:

INSPIRE 6M: Hollow Fiber Oxygenator

INSPIRE 6M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 6M is intended to be used for 6 hours or less.

INSPIRE HVR: Hardshell Venous/Cardiectomy Reservoir


INSPIRE HVR is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood. INSPIRE HVR can be used post-operatively for chest drainage. INSPIRE HVR is intended to be used for 6 hours or less.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)



(Division Sign-Off)
Division of Cardiovascular Devices

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